INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

# PCT

To:

REVELL, Christopher Avecia Limited Intellectual Porperty Group P.O. Box 42, Hexagon House Manchester M9 8ZS § GRANDE BRETAGNE

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

IMPORTANT NOTIFICATION

Registered

letter

Date of mailing (day/month/year)

14/04/2004

Applicant's or agent's file reference

SMC 60554/WO

International filing date (day/month/year)

Priority date (day/month/year)

International application No.

PCT/GB03/04312

08/10/2003

15/10/2002

Applicant

AVECIA BIOTECHNOLOGY INC. et al.

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application. 1.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the 2. elected Offices.

Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices. 3.

INITIALS DATE DATE ENTERED INTO 19/11/04 65 (EN-IP SK REMINDER CREATED UR ATTORNEY

REMINDER 4.

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office; that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's

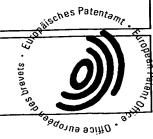
The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/

European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465 Authorized officer

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# INTERNATIONAL SEARCH REPORT

International Application No

		1/68 03/	04217
A. CLASSIF IPC 7	CO7H19/06 CO7H19/16 CO7F9/24		
According to	International Patent Classification (IPC) or to both national classifical	tion and IPC	
B FIFI DS S	SEARCHED		
Minimum doo IPC 7	cumentation searched (classification system followed by classificatio ${\tt C07H} {\tt C07F}$		
Documentati	on searched other than minimum documentation to the extent that su	uch documents are included in the fields sea	arched
Electronic da	ata base consulted during the international search (name of data bas	se and, where practical, search terms used)	
EPO-Int	ternal, WPI Data, PAJ, CHEM ABS Data		
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT		Relevant to claim No.
Category °	Citation of document, with indication. where appropriate, of the rele	evant passages	I IS IS VALUE OF COMMITTEE
А	US 6 275 725 B1 (COSMAN ERIC R) 14 August 2001 (2001-08-14) the whole document		
А	US 5 034 534 A (MILSTEIN DAVID) 23 July 1991 (1991-07-23) the whole document		
P,X	WO 03 004512 A (AVECIA LTD ;MIRAN GREGORY KEITH (US); SINHA NANDA ( AVECIA B) 16 January 2003 (2003-0 the whole document	(US);	1-13
			-
Furt	ther documents are listed in the continuation of box C.	Patent family members are listed	I in annex.
<ul> <li>Special categories of cited documents:</li> <li>'A' document defining the general state of the art which is not considered to be of particular relevance</li> <li>'E' earlier document but published on or after the international filing date invention</li> <li>'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>'O' document referring to an oral disclosure, use, exhibition or other means</li> <li>'P' document published prior to the international filing date but</li> <li>'S' document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>'X' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is taken alone</li> <li>'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents; such combination being obvious to a person skilled in the art.</li> <li>'B' document member of the same patent family</li> </ul>			claimed invention of the considered to ocument is taken alone claimed invention nventive step when the lore other such docu-
later	than the priority date claimed	Date of mailing of the international se	
	e actual completion of the international search	05/02/2004	•
<u> </u>	28 January 2004	Authorized officer	
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL - 2280 HV Rijswijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  Fax: (+31-70) 340-3016		Klein, D	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No T/GB 03/04312

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 6275725	B1	14-08-2001	US US US US US US US	5662111 A 6351661 B 6006126 A 5848967 A 6675040 B 2002065461 A 2002188194 A 6405072 B	1 51 51	02-09-1997 26-02-2002 21-12-1999 15-12-1998 06-01-2004 30-05-2002 12-12-2002 11-06-2002
US 5034534	Α	23-07-1991	NONE			
WO 03004512	 А	16-01-2003	WO	03004512 A	<b>\1</b>	16-01-2003



# INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference  FOR FURTHER see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.					
SMC 60554/W0 International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)			
PCT/GB 03/04312	08/10/2003	15/10/2002			
Applicant		•			
, 45					
AVECIA BIOTECHNOLOGY INC.					
This International Search Report has bee according to Article 18. A copy is being tr	n prepared by this International Searching Aut ansmitted to the International Bureau.	thority and is transmitted to the applicant			
This International Search Report consists  It is also accompanied by	s of a total of3 sheets.  If a copy of each prior art document cited in this	s report.			
Basis of the report					
<ul> <li>With regard to the language, the language in which it was filed, ur</li> </ul>	international search was carried out on the balless otherwise indicated under this item.	asis of the international application in the			
Authority (Rule 23.1(b)).	was carried out on the basis of a translation of				
b. With regard to any <b>nucleotide a</b> was carried out on the basis of the	nd/or amino acid sequence disclosed in the i	international application, the international search			
contained in the internati	onal application in written form.				
filed together with the int	ernational application in computer readable for	rm.			
furnished subsequently t	o this Authority in written form.				
furnished subsequently t	o this Authority in computer readble form.				
international application	ubsequently furnished written sequence listing as filed has been furnished.				
the statement that the in furnished	formation recorded in computer readable form	is identical to the written sequence listing has been			
2. Certain claims were fo	und unsearchable (See Box I).				
3. Unity of invention is la	cking (see Box II).				
4. With regard to the <b>title</b> ,					
1 1 1	submitted by the applicant.	·			
the text has been establ	ished by this Authority to read as follows:				
5. With regard to the abstract,					
<u> </u>	submitted by the applicant. lished, according to Rule 38.2(b), by this Autho he date of mailing of this international search r	ority as it appears in Box III. The applicant may, report, submit comments to this Authority.			
	blished with the abstract is Figure No.	1			
X as suggested by the ap		None of the figures.			
l hl	ailed to suggest a figure.				
1 —	er characterizes the invention.				

# From the INTERNATIONAL SEARCHING AUTHORITY

To: AVECIA LIMITED

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT

Intellectual Property Group Attn. Revell, Christopher PO Box 42, Hexagon House Blackley Manchester M9 8ZS UNITED KINGDOM	OR THE DECLARATION  (PCT Rule 44.1)  Date of mailing (day/month/year)  05/02/2004			
Applicant's or agent's file reference				
SMC 60554/WO	FOR FURTHER ACTION See paragraphs 1 and 4 below			
International application No.	International filing date (day/month/year)			
PCT/GB 03/04312	(day/month/year) 08/10/2003			
Applicant				
AVECIA BIOTECHNOLOGY INC.	· · · · · · · · · · · · · · · · · · ·			
The applicant is hereby notified that the International Searce  Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claim.	ch Report has been established and is transmitted herewith.  ms of the International Application (see Rule 46):			
When? The time limit for filing such amendments is norm International Search Report; however, for more d	etails, see the notes on the accompanying ones.			
Where? Directly to the International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41–22) 740.14.3	31210			
For more detailed instructions, see the notes on the acc	ompanying sheet:			
2. The applicant is hereby notified that no International Search Article 17(2)(a) to that effect is transmitted herewith.	ch Report will be established and that the declaration under			
3. With regard to the protest against payment of (an) addit	on transmitted to the International Bureau together with the			
applicant's request to forward the texts of both the pr	otest and the decision thereon to the designated Silvers.			
no decision has been made yet on the protest; the ap	pplicant will be notified as soon as à decision is made.			
4. Further action(s): The applicant is reminded of the following				
Shortly after <b>18 months</b> from the priority date, the international application will be published by the Internat <sup>**</sup> all Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 <i>bis</i> .1 and 90 <i>bis</i> .3, respectively, before the completion of the technical preparations for international publication.				
Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).				
Within 20 months from the priority date, the applicant must peribefore all designated Offices which have not been elected in priority date or could not be elected because they are not bou	the definated of the a later election within 10 months with			

Name and mailing address of the International Searching A	
	Furnacia Potont Office P.R. 5818 Patentlaan 2

European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Authorized officer

Kerstin G<sup>^</sup>tz





These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

# INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

## What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been fis filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

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The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

# The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
   "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]:
   "Claims 1 to 15 replaced by amended claims 1 to 11."
- 3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
  "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
  "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4. [Where various kinds of amendments are made]: "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14, claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

## It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

## Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

## Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

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Notes to Form PCT/ISA/220 (second sheet) (January 1994)